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10/767,962	01/26/2004	Helga Biergiesser	104035.273254	5690

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EXAMINER	
HARLE, JENNIFER I	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,962	BIERGIESSER ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13, 14-18 and 34-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 34-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/08/05;09/02/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13, 15-18 and 34-48 are pending.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Arguments

3. *Claims 1-13, 15-18, 34-35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.*

Applicant's arguments have been fully considered but are not deemed persuasive. While Applicants argue that one of ordinary skill would readily understand the scope of the salts and the esters the examiner respectfully disagrees because of the limited guidance as previously set forth and no examples. A more full analysis is set forth below. Additionally, a new written description rejection of the creatinine derivatives is set forth below, as well as an enablement rejection for creatine salts and creatine esters and creatinine derivatives.

4. *Claims 1-11, 17-18, 36-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Howard, et al. (US 5,968,544), cited by Applicant.*

These rejections is withdrawn in light of Applicants' Amendments.

5. *Claims 12-13, 15, 16, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, et al. (US 5,968,544), cited by Applicant.*

These rejections are withdrawn in light of Applicants Amendment and arguments.

6. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, et al. (US 5,968,544), cited by Applicant in view of Cohn (US 5,576,316).

These rejections are withdrawn in light of Applicants Amendment and arguments.

7. Claims 1-6, 8-13, 17-18, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk (US 6,242,491 B1) in view of Yu, et al. (US 5,883,128).

The rejection is withdrawn in light of Applicants' arguments.

8. Claims 1-6, 8-13, 17-18, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk (US 6,242,491 B1) in view of Yu, et al. (US 5,883,128).

The rejection is withdrawn in light of Applicants' arguments.

9. Claims 1-11, 18, 36-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Honda, et al. (4,970,072) or Gardlik, et al. (US 2002/0119174) in view of D. Venkatappaiah, et al. Nonprotein nitrogenous constituents of Milk. I. Variation due to species, breed, individuality, season, and stage of lactation, Indian Journal of Dairy Science, 1952, Vo. 5, pp. 95-116 (Abstract Only).

The rejection is withdrawn in light of Applicants' Amendment.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims1-13, 15-18, 34-36, 38-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those

specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

In the instant case, the claims are drawn to a cosmetic or dermatological preparation for various uses comprising a content of an active ingredient combination consisting of creatinine and derivatives there of in combination of at least one compound selected from the group consisting of creatine, creatine salts and creatine esters

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art varies but is typically high as you are making pharmaceutical (dermatological) and cosmetic products that affect symptoms of skin damage that will have different etiologies. Creating the plethora of libraries of creatinine derivatives is not

difficult, nor is creating the libraries of creatinine salts or esters or making the same. However, formulating them into dermatological and/or cosmetic compositions, where they are the active ingredients within the particular formulations is, as it require knowledge of their interactions together and with any additives and their effects upon the various conditions and upon the skin or if ingested pharmakodynamics.

(2) Partial structure:

The partial structures provided would be those able to be determined by the names creatinine, the specific salts given, i.e. creatine phosphate, creatine sulphate, creatine acetate, and creatine ascorbate (partial structure would be substitution at the hydrogen). See pg. 7 and 8 of the Specification. As to the creatine esters the only description is of esterification on the carboxyl group with mono or polyfunctional alcohols.

(3) Physical and/or chemical properties:

No physical or chemical properties are provided for the creatinine derivatives. In fact no definition whatsoever is provided.

(4) Functional characteristics:

The combination of the active ingredients is disclosed to treat or prevent (prophylaxis) a multitude of skin disorders. However, they are not directly linked to the creatinine derivatives, creatine salts or creatine esters.

(5) Method of making the claimed invention:

Applicants' disclose multiple ingredients and potential ranges of ingredients that could be used to formulate cosmetic and dermatological preparations "having an effective content of active ingredient used according to the invention to the affected area of the skin." Pg. 12, lines 1-

2. Applicants do provide 5 PIT emulsions but they do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester; 10 examples of O/W emulsion cream but again do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester; 7 examples of W/O emulsions but they do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester; 5 examples of hydrodispersions but they do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester; 1 example of a gel cream but they do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester; 1 example of a W/O cream but they do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester; and 1 example of W/O/W cream but they do not teach how to make them and they are only for creatinine and creatine – there is **not one example** of any derivative, salt or ester. Moroever, while Applicants state that these examples severe to illustrate the present invention, there is absolutely no teaching that these compositions are in any way useful as cosmetic or dermatological product or that they will treat or prevent any skin condition.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 1-13, 15-18, 34-36, 38-48 are to broad generics, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any classes of creatinine derivatives (which could encompass any compounds as a derivative is merely "a chemical substance that derived from another substance either directly or by modification or partial

substitution and without any direction, it could be any component part, i.e. hydrogen/nitrogen/carbon or substituted with salts/amides/esters/peptides/mimetics/amino acids/sugars/alcohols, etc. there is absolutely no limitations); the possible structural variations are unlimited any class of creatine salts they do not have to be simple inorganic or organic salts they can encompass peptide salts, amino acid substituted salts and the salt does not necessarily have to be substituted at the terminus there can be disodium salts, etc.; and as the possible structural variations of creatine esters it is unknown since it is unclear what would even be encompassed by the term polyfunctional alcohols. Though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives or esters and lacks any correlation between the deriviates, esters and salts and their functionality. Applicants have written description of creatine and creatinine and compounds identified in the specification tables and/or examples, the specification is void of any peptides, organic molecules that qualify for the functional characteristics claimed as the derivatives, salts and esters, with functional characteristics that qualify.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed

that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

12. Claims 1-13, 15-18, 34-36, 39-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cosmetic and dermatological compositions comprising creatinine and creatinine and creatinine and creatinine phosphate/sulphate/acetate/ascorbate, does not reasonably provide enablement for cosmetic or dermatological compositions comprising creatinine and creatine salts; creatinine and creatine esters; creatinine derivatives and creatine salts; and creatinine derivatives and creatine esters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention **commensurate in scope** with these claims.

The claims are directed to cosmetic or dermatological preparations comprising an active ingredient composition of creatinine and its derivatives in combination with creatine, creatine salts, and creatine esters. The specification fails to adequately teach how to make and use the cosmetoic or dermatological preparation.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 were the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPA 546 (BdApls 1986) at 547 the court recited the eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6)

the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity or experimentation necessary.

(1) The Nature of the Invention:

The rejected claims are drawn to cosmetic or dermatological preparations comprising creatinine and creatine salts; creatinine and creatine esters; creatinine derivatives and creatine salts; and creatinine derivatives and creatine esters.

(2) The Breadth of the Claims:

The instant claims are drawn to five groups which contain three different genus – creatinine salts, creatine esters, and creatinine derivatives. Each genus contains a plethora of undisclosed, structurally unknown species. Creatine salts are unlimited any class of creatine salts they do not have to be simple inorganic or organic salts they can encompass peptide salts, amino acid substituted salts and the salt does not necessarily have to be substituted at the terminus there can be disodium salts, etc. The possible variations of creatine esters is unknown since it is unclear what would even be encompassed by the term polyfunctional alcohols and one could potentially create an ester at a point other than the terminus. The potential reatinine derivatives are limitless as a derivative is merely a chemical substance that derived from another substance either directly or by modification or partial substitution and without any direction, it could be any component part, i.e. hydrogen/nitrogen/carbon or substituted with salts/amides/esters/peptides/mimetics/amino acids/sugars/alcohols, etc. Thus, there is absolutely no determining the limitations.

(3) Guidance of the Specification/Working Examples:

In the instant case there are no working examples presenting the specification showing any of the creatine salts, creatine esters, or creatinine derivatives. Moreover, the only guidance about presented about any genus is that for the salts is that the preferred salt is creatine phosphate and that three others can be used, i.e. creatine sulphate, creatine ascorbate and creatine acetate and that the esters can be prepared by esterification using mono or polyfunctional alcohols. There is no guidance as to how to pick which salts or esters to use, what characteristics are likely to be functional, screening, or guidance on combination with creatinine derivative. As to guidance on the creatinine derivatives none is provided – there is no definition, no assay for functionality, no guidance in determining which ones might work in the cosmetic or dermatological fields.

(4) State/Predictability of the Art:

The level of skill and knowledge in the art varies but is typically high as you are making pharmaceutical (dermatological) and cosmetic products that affect symptoms of skin damage that will have different etiologies. Creating the plethora of libraries of creatinine derivatives is not difficult, nor is creating the libraries of creatinine salts or esters or making the same. However, formulating them into dermatological and/or cosmetic compositions, where they are the active ingredients within the particular formulations is, as it require knowledge of their interactions together and with any additives and their effects upon the various conditions and upon the skin or if ingested pharmakodynamics is complex. What is known for one compound when combined with another would not necessarily hold true and as you are using these for cosmetic or dermatological purposes the skilled artisan would view the whole process as involving a moderate to high level of unpredictability.

(5) The Quantity of Experimentation Necessary:

There are no working examples provided for any of the three genus. Moreover, they have to be combined with each other and with creatine or creatinine. In addition, there are other ingredients that go into making these compounds. It would require a lot of experimentation to first make an acceptable grade of the product, determine the correct combinations of the compounds and their efficacy without harm to the skin, as Applicant fails to provide any information or guidance regarding any of the salts, esters or derivatives. Therefore, applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation.

Therefore, in view of the Wands factors, e.g. the amount of direction or guidance provide, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to create, make and test the variety of combinations of creatinine derivatives and creatine; creatinine derivatives and creatine salts; creatinine derivatives and creatine esters; creatinine and creatine salts; creatinine and creatine esters in cosmetic or dermatological preparations, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-18, 36, and 39-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "creatinine and derivatives thereof" in claim 1 renders the claims indefinite. The recitation, "creatinine and derivatives thereof" or creatinine derivatives is not defined in the specification. Hence, one of ordinary skill in the art could not

ascertain and interpret the metes and bounds as to creatinine derivatives, , since one of ordinary skill in the art would clearly recognize many chemical substances that could be derived from creatinine either directly or by modification or partial substitution of creatinine according to it structural formula as set forth in the specification. See the written description rejection and enablement rejection above.

14. Claims 1-18, 36, and 39-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "creatine esters" encompasses "mono" or "polyfunctional" alcohols and as such renders the term vague and indefinite, as it is not clear what other compounds this term encompasses, since one of ordinary skill in the art could not ascertain the metes and bounds as "polyfunctional" alcohols. It is unclear as to what compounds are encompassed by the term polyfunctional alcohols."

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-15, 17-18, 34-38, 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk (US 6,242,491 B1) in view of Lion Corporation (JP 2000-247886) (English Translation provided).

Kaddurah-Daouk discloses the use of creatine, creatine phosphate or analogs of creatine for protecting skin tissue against age related damage or insults, harmful UV radiation, stress and

fatigue and would include wrinkles, loss of elastisticity of the skin and uneven pigmentation of the skin, and even mitochondrial disfunction. Abstract, Col. 2, lines 15-28, col. 3, lines 19-25 and 43-52, col. 4, lines 1-14, Col. 8, lines 35-43, col. 14, lines 38-50, Claims 1, 6-9, 11-16, 18, 20, 25, 29-32. Additionally, Kaddurah-Daouk discloses that topical pharmaceutical compositions of the present invention may be contain from about 0.1% to about 50% of the active compound and from about 2% to about 50% of a topical pharmaceutically-acceptable emollient and if a lotion can comprise from about 0.1% to about 20% of the active compound. Col. 5, lines 45-65. Kaddurah-Daouk also discloses that the creatine compound may be used in skin cleaning compositions as an active ingredient. Col. 8, lines 10-16. Kaddurah-Daouk further discloses that the selected dosage level will depend upon a variety of factors including the activity of the particular compound of the present invention employed, or the ester, salt or amide thereof, the route of administration, the time of administration , the rate of excretion of the particular compound being employed, the duration of the treatment, other drugs, compounds and/or materials sued ,etc. as is well known in the art. Col. 13, lines 56-67. Kaddurah-Daouk further discloses that the cosmetic or dermatological preparation can be in the form of a solution, water-in-oil emulsion, oil-in-water emulsion, wat-in-oil-in-water emlusions, gel, solid sticks, creams,[1] lotions, aerosols, and sunscreen lotions. See col. 2, lines 27-29, col. 4, lines 19-27, col. 5, lines 14-18, col. 6, lines 47-55. Moreover Kaddurah-Daouk discloses that the cosmetic or dermatological preparation can contain fillers, vitamins, antioxidants,, UVA filter, UVB filter and inorganic pigments. See cols. 8-9, lines 30-38, col. 7, lines 28-33. Finally, Kaddurah-Daouk

[1] As these creams/lotions are used for dermatological purposes and sunscreens they would implicitly by skin protection creams, nourishing creams, day creams, or night creams as per claim 42 as they do not have any additional ingredients to differentiate them and sunscreens and vitamin additives and antioxidants are taught as set forth above.

discloses that the creatine compound can be administered to the afflicted individual alone or in combination with another creatine analog or other agent, which would include those that protect against oxidative damage, energy enhancers sugars, intermediates of metabolism and nutrients among others. Col. 25, lines 60-62. However, Kaddurah Daouk does not disclose the use of creatinine and derivatives thereof in combination with the creatine. Lion discloses that external skin preparations can be made utilizing as active ingredients creatinine and/or creatine, in amounts of 0.05-5% of the weight, preferably 0.01-10% of the weight because the effectiveness of less than 0.01% of the weight is insufficient and when 10% of the weight is exceeded the stability becomes questionable. Claim 1, [0004], [0005], [0008]. Lion further teaches that the composition can be used as an antioxidant, i.e. against oxidative damage, contain an antioxidant, vitamins [0007], [0010], [0012]. Lion discloses that additional componentions can include perfume, coloring matter (pigments), water, and can be made into emulsifications (wter-oil)creams, milky lotion, lip stick (solid stick). [0023], [0024]. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). Moreover, Lion discloses that they can be used together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

November 5, 2005